

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>
<b>THIS DOCUMENT RELATES TO: WAVE 8 CASES ON ATTACHED EXHIBIT A</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION  
TO EXCLUDE CERTAIN OPINIONS OF DR. DOROTHY KAMMERER-DOAK**

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' expert, Dorothy Kammerer-Doak, M.D. In support of their Motion, Plaintiffs state as follows:

**INTRODUCTION**

Dr. Zaslau is board certified in obstetrics and gynecology and certified in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery. Exhibit B, Report, Reliance and CV, at p. 1 of CV. Plaintiffs do not challenge her qualifications as such. However, Dr. Kammerer-Doak seeks to offer testimony that is not helpful for the jury, clearly exceeds the bounds of her qualifications, and is founded on insufficient facts and unreliable methodology.<sup>1</sup> Specifically, this Court should exclude Dr. Zaslau's opinions regarding: (1) the adequacy of Defendants' product warnings and IFUs, including opinions regarding what risks of the devices other doctors know of; (2) whether the product at issue is associated with chronic or long term pain; and

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<sup>1</sup> See *Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.).

(3) any opinion regarding safety, efficacy, or personal satisfaction rates of the mesh products observed in her own practice.

### LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by “knowledge, skill, experience, training or education.” Fed. R. Evid. 702. The witness’s testimony also must represent “scientific knowledge,” meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) “will help the trier of fact to understand the evidence or to determine a fact in issue,” (2) is “based upon sufficient facts or data,” (3) is “the product of reliable principles and methods” and (4) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. Opinion evidence may be admitted if it “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597. In the end, an expert’s testimony is admissible if it “rests on a reliable foundation and is relevant.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with Dr. Kammerer-Doak to proffer expert testimony and “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if the expert is qualified and her testimony is reliable, “testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, her testimony must “fit” the

case, and there must be a “valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id.*

## ARGUMENT

### **1. Dr. Kammerer-Doak’s opinions on the adequacy of defendants’ warnings and what other doctors know about the risks of pelvic mesh devices should be precluded pursuant to *Daubert***

Dr. Kammerer-Doak’s testimony is unreliable as she admits her opinions on the adequacy of defendants’ warnings are based on nothing more than personal convictions regarding what risks are commonly known to physicians about the device and not based on any industry standards or regulations governing the adequacy of warnings. Thus, they are thus *ipse dixit* and precluded under *Daubert*. Dr. Kammerer-Doak had no independent knowledge of FDA requirements and no knowledge of industry standards governing the adequacy of warnings and instructions for use while authoring her report in this case.

Prior to authoring her report and issuing her opinions, she did not review any documents on industry standards or regulations related to medical device instructions for use or adequacy of warnings statements and she was not aware of what was supposed to be in the instructions for use. Dr. Kammerer-Doak, Dep. Tr., 115:1-15. Plaintiff’s Motion, Exhibit C. She testified she has no idea why Ethicon changed the IFU and warnings over time. *Id.* 123:24-124:3. Finally, she actually testified she does not know what IFU stands for. 128:24-129:6.

In contradiction to the standards she did not review prior to issuing her opinions, she testified companies need to warn of risks associated with a device if the risks are commonly known by surgeons. 159:15-20. But she admits she performed no independent research at all on standards of any kind before publishing her expert report and attempts to shoehorn into evidence the same type of testimony by providing impermissible, speculative testimony regarding what risks he

believes “all doctors” knew or did not know about the device, while admitting she has not used any reliable methodology in arriving at that conclusion. Such testimony lies at the heart of what *Daubert* and its progeny have found inadmissible.

This Court is obliged to exercise a “gatekeeping” function to ensure that expert testimony is both relevant and reliable. FED. R. EVID. 702; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). This obligation applies to all types of expert testimony, not merely scientific analysis. *Kumho Tire*, 526 U.S. at 149; *Holsesapple v. Barrett*, No. 00-1537, 2001 WL 208490, at \*1 (4th Cir. 2001). The proponent of the testimony has the burden of proving both relevance and reliability. *Bickel v. Pfizer, Inc.*, 431 F. Supp. 2d, 918, 921 (N.D. Ind. 2006). While an expert who is a urologist or pelvic floor surgeon may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at \*14 (S.D. W. Va. Feb. 7, 2015). Dr. Kammerer-Doak does not possess the additional expertise to offer expert testimony about what an IFU should or should not include, and therefore, her testimony regarding these issues should be excluded.

Dr. Kammerer-Doak testified she did no analysis herself on the subject and that all materials on her reliance were supplied to her by Ethicon. 18:19-25. Importantly, an article that contradicts her opinions and has been used a multiple prior mesh trials on this very subject, she did not review prior to issuing her opinions in this case. She testified she had not reviewed literature discussing doctors do not know the complications associated with transvaginal mesh devices. 124:16-125:3, 125:14-21.

As this Court held in *Sanchez*: “[a]n expert’s opinion may be unreliable if he fails to account for contrary scientific literature and instead ‘selectively [chooses] his support from the scientific landscape.’ ‘[I]f the relevant scientific literature contains evidence tending to refute the expert’s theory and the expert does not acknowledge or account for that evidence, the expert’s opinion is unreliable.’”<sup>2</sup>

Dr. Kammerer-Doak appears to have relied solely on material fed to her by counsel for Defendants for her opinions, which she only reviewed after issuing her report, and done no independent research to verify that there are other materials that contradict her opinion. Dr. Kammerer-Doak, Dep. Tr., 115:1-15. Federal courts have consistently held that *ipse dixit* – opinions justified solely by the fact that the expert holds them -- are inadmissible. *See, e.g., GE v. Joiner*, 522 U.S. 136, 146 (1997); *see also Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011) (“If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong.”) The Fourth Circuit concurs. *Holesapple*, 2001 WL 208490 at \*2 (“[I]t still is a requirement that the expert opinion evidence be connected to existing data by something more than the ‘it is so because I say it is so’ of the expert.”). This Court has also excluded *ipse dixit* opinions. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D.W. Va. 2013).

To be admissible, expert testimony must explain the link between the available evidence or data and the expert’s opinion. *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir. 2001); *see also Cunningham v. Masterwear, Inc.*, No. 1:04-cv-1616-JDT-WTL, 2007 WL 1164832, at \*9 (S.D. Ind. Apr. 19, 2007) (“It is not enough for an expert to say this is my data and that is my

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<sup>2</sup> *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189, \*70 (S.D. W. Va. Sept. 29, 2014) (citations omitted).

conclusion without connecting the two.”); *Mid-State Fertilizer Co. v. Exchange Nat. Bank of Chicago*, 877 F.2d 1333, 1390 (7th Cir. 1989) (“An opinion has a significance proportioned to the sources that sustain it.”).

Similarly, in this case, Dr. Kammerer-Doak’s testimony on the product warnings, by her own admission, is not based on any objective standard, regulation or analysis, did not include a review of contradictory materials on the subject, and were based solely on materials provided by the Defendants which the doctor is not qualified to opine on and did not ever review prior to issuing her opinions in this case. Those opinions are thus inadmissible under the *Daubert* line of cases.

## **II. Dr. Kammerer-Doak’s opinion that the TVT is not associated with chronic or long-term pain is completely unsupported, and therefore, unreliable**

Dr. Kammerer-Doak testified that she has never once in her practice seen a mesh sling cause pain to a patient. 89:1-18. And that in examining thousands of women with pelvic and vaginal pain, she has not seen a single case where a mesh sling caused pain and has never seen a single patient who had pain at the site of the mesh sling. 90:6-15, 91:3-9.

But when asked to provide support in the scientific literature for that opinion, Dr. Kammerer-Doak could not do so. She testified there is not a single randomized clinical trial that was powered to detect long-term pelvic pain from the TVT. 103:20-25

That is simply not a reliable basis for a biomedical opinion. This Court has previously rejected this sort of “I have not seen it, therefore it must not happen” logic. Indeed, in ruling on *Daubert* motions in *Tyree*, the Court held that the “[a]bsence of evidence is not evidence of absence,” and refused to allow defendant’s expert to opine that certain events do not occur simply because he had not observed them in her practice.<sup>3</sup> By that same unassailable reasoning,

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<sup>3</sup> *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014)).

Dr. Kammerer-Doak's claim she has never seen pain caused by the TVT cannot serve as a reliable scientific basis for rendering the opinion that it did not occur. Therefore, this unscientific testimony should be excluded. Especially considering, the fact she does not track her TVT patients in the short-term or long-term, and has no system to track her TVT implants or patient follow-up. 64:15-66:11. Moreover, Dr. Kammerer-Doak has never published any literature on transvaginal mesh, slings or the TVT, nor anything on stress urinary incontinence. Dr. Kammerer-Doak, Dep. Tr., 03-07-2017, 38:2-9, 42:25-43:10, 46:20-47:1 Plaintiff's Motion, Exhibit D. This despite the fact, she only currently sees patients one week out of the month, does not currently use the TVT and has not used the TVT in several years. *Id.* at 59:21-24, 60:6-11, 60:17-20

Moreover, this type of "no it's not" *ipse dixit* testimony is not helpful to the jury—because it provides no scientific basis upon which the jury could rely.<sup>4</sup> Neither *Daubert* nor the Federal Rules of Evidence require the admission of opinion evidence that is merely *ipse dixit* of the expert, and a court may conclude that there is too large of an analytical gap between the data and the opinion proffered.<sup>5</sup> Again, Dr. Kammerer-Doak's opinions amount to nothing more than the type of "unsupported speculation" that must be excluded under *Daubert*.<sup>6</sup>

**III. Dr. Kammerer-Doak's opinion about her personal experience related to the safety and efficacy of the TVT should be excluded because they are not based on any objective standard, and her analysis and methodology are flawed**

Dr. Kammerer-Doak should be precluded from testifying about her perceived safety, efficacy, and patient satisfactions rates with the subject products from her practice, as those

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<sup>4</sup> *Ipse dixit* is defined as "[h]e himself said it; a bare, assertion resting on the authority of an individual." See Black's Law Dictionary 828 (6th ed. 1990); see also *Sadow-Pajewski v. Busch Entertainment Corp.*, 55 F. Supp. 2d 422, 427 (E.D.Va. 1999).

<sup>5</sup> *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

<sup>6</sup> *Brown*, 1997 U.S. App. LEXIS 23559 at \*3 (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); see also *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

opinions are entirely unsupported by any reliable methodology, nor have they been subject to peer review. This court has already ruled that an expert cannot relate precise statistics based on their own assurances that those statistics are reliable. *In re Ethicon*, 2016 WL 4542054 (S.D. W. Va. 2016).

In arriving at her opinion, Dr. Kammerer-Doak admits she has not done any kind of survey regarding the patient satisfaction of her TVT patients and she does not track her TVT patients in the short-term or long-term, and has no system to track her TVT implants or patient follow-up. 64:15-66:11. Moreover, Dr. Kammerer-Doak has never published any literature on transvaginal mesh, slings or the TVT, nor anything on stress urinary incontinence documenting her own supposed clinical experience. Dr. Kammerer-Doak, Dep. Tr., 03-07-2017, 38:2-9, 42:25-43:10, 46:20-47:1 Plaintiff's Motion, Exhibit D.

Moreover, she testified she only currently sees patients one week out of the month, does not currently use the TVT and has not used the TVT in several years. *Id.* at 59:21-24, 60:6-11, 60:17-20.

Dr. Kammerer-Doak's opinions about patient satisfaction and adverse event rates among her own patients is inappropriate, unsupported and inadmissible and exactly the kind of foundationless testimony this court has excluded in the past. She lacks any reliable methodology or analysis to support his conclusions. In addition, allowing Dr. Kammerer-Doak to offer an opinion as to his patient satisfaction rate and "significant adverse event rate" for her own patients would be confusing and misleading to a jury when considering the question of whether or not the mesh devices in question defective, and should be excluded under Rule 403. Because there is no foundation for his opinions, Dr. Kammerer-Doak should be prohibited from providing this testimony.



## CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Kammerer-Doak is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in the opinions discussed above, Ethicon cannot carry this burden and his testimony should be accordingly limited.

Dated: October 18, 2018

Respectfully submitted,

/s/Thomas P. Cartmell

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 18, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/Thomas P. Cartmell